IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDNA MALONZO,

Plaintiff,

v.

MENTOR WORLDWIDE, LLC and DOES 1-25,

Defendants.
_____/

No. C 14-01144 JSW

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

Now before the Court is the motion to dismiss filed by Defendant Mentor Worldwide LLC ("Defendant"). The Court finds that this matter is appropriate for disposition without oral argument and is deemed submitted. *See* N.D. Cal. Civ. L.R. 7-1(b). Accordingly, the hearing set for June 6, 2014 is hereby VACATED. Having carefully reviewed the parties' papers, considered their arguments and the relevant legal authority, the Court hereby grants Defendant's motion to dismiss.[1]

BACKGROUND

Plaintiff Edna Malonzo ("Plaintiff") brings state-law claims based on injuries she sustained when the saline breast implants, manufactured by Defendant, leaked and caused a mycobacterial infection. (Compl., ¶ 4.) Plaintiff alleges that before she had the product surgically implanted, Defendant new that its product was extremely dangerous and unsafe and that Defendant failed to take appropriate action to cure the defects or to warn the users of this product or their physicians. (*Id.*, ¶ 8.) Plaintiff asserts claims for strict product liability,

[1] The Court GRANTS Defendant's request for judicial notice. *See* Fed. R. Evid. 201.

negligence, breach of express warranty, breach of implied warranty, negligent misrepresentation, *res ipsa loquitor*, and fraud. Defendant argues that all of Plaintiff's claims are preempted by Section 360k of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"). Plaintiff, in her opposition, does not offer any argument that her claims as currently pled are not preempted. Instead, Plaintiff merely seeks leave to amend. The Court will address additional facts as necessary in the remainder of this Order.

ANALYSIS

A. Applicable Legal Standards.

A motion to dismiss is proper under Federal Rule of Civil Procedure 12(b)(6) where the pleadings fail to state a claim upon which relief can be granted. The Court construes the allegations in the complaint in the light most favorable to the non-moving party and all material allegations in the complaint are taken to be true. *Sanders v. Kennedy*, 794 F.2d 478, 481 (9th Cir. 1986). However, even under the liberal pleading standard of Rule 8(a)(2), "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must instead allege "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S.662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully.... When a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted). If the allegations are insufficient to state a claim, a court should grant leave to amend, unless amendment would be futile. *See, e.g., Reddy v. Litton Indus., Inc.*, 912 F.2d 291,

296 (9th Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 246-47 (9th Cir. 1990).

Where, as here, a plaintiff pleads a claim for fraud, he must also satisfy the requirements of Rule 9(b). Under Rule 9(b), claimants must allege with particularity the circumstances constituting fraud. *Moore v. Kayport Package Exp., Inc.*, 885 F. 2d 531, 540 (9th Cir. 1989). The claimant satisfies the heightened particularity requirement if the allegations in his complaint "identif[y] the circumstances constituting fraud so that a defendant can prepare an adequate answer from the allegations." *Id.* Averments of fraud must be accompanied by "the who, what, when, where, and how" of the misconduct charged. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

B. Defendant's Motion.

This lawsuit arises from the injuries allegedly caused by saline breast implants, a Class III medical device. MDA "divides medical devices into three classes according to user risk." *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013). Class III medical devices pose the greatest risk, and are subject to a rigorous "pre-market approval ["PMA"] process" of the Federal Drug Administration ("FDA"). *Id.*

The PMA process results in a denial, an approval or an approval "with conditions on distribution, marketing or sale." *Id.* The PMA process includes a "risk-benefit assessment of the device." *Id.* Thus, the FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008).

Even after pre-market approval is granted, there are post-approval statutory and regulatory requirements the manufacturer must satisfy, in addition to any post-approval conditions the FDA imposes on the specific device subject to the PMA. In general, the manufacturer must refrain from manufacturing, packaging, storing, labeling, distributing or advertising the medical device "in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. In addition, the manufacturer must report deaths and serious injuries that the device "has or may have caused or

contributed to" and certain device malfunctions, and it "must establish and maintain adverse event files," and "submit specified followup." 21 C.F.R. §§ 814.84(a) (must comply with Part 803 reporting requirements); 803.1(a) (general statement of reporting requirements).

The MDA contains the following explicit preemption clause:

> [N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement–
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device; and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has applied a two-step analysis to determine whether the MDA expressly preempts a state law claim within the meaning of §360k(a). *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). First, a court must determine whether the MDA has established federal "requirements" applicable to the particular medical device at issue. *Id*. at 321. This step is clearly satisfied by the PMA process here for this Class III medical device.

Second, if the MDA does establish federal requirements, a court must then determine whether the state law claims are based on state requirements with respect to the medical device that are "different from, or in addition to" the federal requirements, and relate to safety and effectiveness. *Id*. at 321-22.

"State requirements are preempted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. . . . Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (internal citations omitted); *Stengel*, 704 F.3d at 1228 ("the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA").

Defendant argues that all of Plaintiff's claims are expressly preempted by Section 360k of the MDA. Plaintiff does not proffer any argument to establish that her claims are based on parallel state law requirements. In fact, she concedes that she has not yet stated valid state-law

claims. (Opp. at 3.) Instead, she seeks leave to amend based on her contention that the reporting requirements for Class III medical devices were not met. The Court will provide Plaintiff with leave to amend. However, the Court admonishes Plaintiff that she has not yet stated facts that are sufficient to state a valid state-law claim that would not be preempted.

First, the Court notes that Plaintiff must allege *state-law* requirements that are parallel to the federal requirements. At this point, Plaintiff has only referenced federal requirements and appears to seek to enforce those directly. Second, Plaintiff must show that she was injured from the failure to report. Although she conjectures that Defendant failed to report similar injuries with other patients, she has no facts to support this assumption. At this point, the only failure to report she argues about is with respect to the saline breast implants implanted in her. Any failure to report her injuries or any defects with her implants could not have *caused* her injury. Furthermore, to the extent she seeks to bring any claim for misrepresentation or warranty must allege the content and location of such representation or warranty.

CONCLUSION

For the foregoing reasons, the Court GRANTS Defendant's motion to dismiss, but will provide Plaintiff with leave to amend. Plaintiff shall file her amended complaint, if any, by no later than twenty-one days from the date of this Order.

IT IS SO ORDERED.

Dated: May 28, 2014

JEFFREY S. WHITE
UNITED STATES DISTRICT JUDGE